



PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/559,595
Filing Date	November 30, 2005
First Named Inventor	ONG, John, et al
Art Unit	1654
Examiner Name	Not Yet Assigned Julie Ha
Attorney Docket Number	0501-UTL-0

Sheet 1 of 4

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
J.H.	1	US- 4,476,116	10-09-1984	SHABBIR, T. Anik	
	2	US- 4,847,240	07-11-1989	RYSER, et al	
	3	US- 5,116,817	05-26-1992	SHABBIR, T. Anik	
	4	US- 5,124,314	06-23-1992	COOPER, Garth J. S.	
	5	US- 5,367,052	11-22-1994	COOPER, Garth, et al	
	6	US- 5,512,549	04-30-1996	CHEN, Victor J.	
	7	US- 5,554,388	09-10-1996	ILLUM, Lisbeth	
	8	US- 5,574,008	11-12-1996	JOHNSON, William, et al	
	9	US- 5,788,959	08-04-1998	SINGH, Manish	
	10	US- 5,580,953	12-03-1996	ALBRECHT, Elisabeth, et al	
	11	US- 5,686,411	11-11-1997	GAETA, Laura, et al	
	12	US- 5,705,483	01-06-1998	GALLOWAY, John, et al	
	13	US- 5,788,959	08-04-1998	SINGH, Manish	
	14	US- 5,804,212	09-08-1998	ILLUM, Lisbeth	
	15	US- 5,977,070	11-02-1999	PIAZZA, Christin, et al	
	16	US- 5,981,488	11-09-1999	HOFFMANN, James	
	17	US- 6,294,153	09-25-2001	MODI, Pankaj	
	18	US- 6,391,318	05-21-2002	ILLUM, Lisbeth, et al	
J.H.	19	US- 6,440,392	08-27-2002	STERN, William	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
J.H.	20	JP 1998095738 A	04-14-1998	MORIMOTO, Y., et al		✓
J.H.	21	JP 2000281589 A	10-10-2000	MORIMOTO, Y., et al		✓
	22	WO 99/07404 A1	02-18-1999	BEELEY, Nigel, et al		
	23	WO 99/25727 A2	05-27-1999	BEELEY, Nigel, et al		
	24	WO 99/25728 A1	05-27-1999	BEELEY, Nigel, et al		
J.H.	25	WO 00/41546 A2	07-20-2000	YOUNG, Andrew, et al		

Examiner Signature	/Julie Ha/	Date Considered	07/17/2008
-----------------------	------------	--------------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO

(Use as many sheets as necessary)

Sheet	2	of	4
-------	---	----	---

Complete if Known

Application Number	10/559,595
Filing Date	November 30, 2005
First Named Inventor	ONG, John, et al
Art Unit	1654
Examiner Name	Not Yet Assigned Julie Ha
Attorney Docket Number	0501-UTL-0

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
/J.H./	34	WO 00/66629 A1	11-09-2000	YOUNG, A., et al		
↓	35	WO 01/04156 A1	01-18-2001	LARSEN, B., et al		
	36	WO 01/98331 A2	12-27-2001	GLAESNER, W., et al		
	37	WO 02/47712 A2	06-20-2002	PITTNER, R., et al		
	38	WO 02/48192 A2	06-20-2002	MILLICAN, R., et al		
	/J.H./	39	WO 03/026591 A2	04-03-2003	COWLEY, M., et al	

Examiner Signature	/Julie Ha/	Date Considered	07/17/2008
-----------------------	------------	--------------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known		
				Application Number	10/559,595	
				Filing Date	November 30, 2005	
				First Named Inventor	ONG, John, et al	
				Art Unit	1654	
				Examiner Name	Not Yet Assigned Julie Ha	
Sheet	3	of	4	Attorney Docket Number		0501-UTL-0

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/J.H./	40	CALLENS, C., et al, "Evaluation of Starch-Maltodextrin-Carbopol 974 Mixtures for the Nasal Delivery of Insulin in Rabbits", J. Control Release, 2000, pp 215-220, Vol. 66(2-3)	
	41	DAVIS, S. and ILLUM, L. "Absorption Enhancers for Nasal Drug Delivery" Clin Pharmacokinet., 2003, pp 1107-1128, Vol. 42(13) Reference not submitted.	
/J.H./	42	DYER, A.M., et al, "Nasal Delivery of Insulin Using Novel Chitosan Based Formulations: A Comparative Study...", Pharm Res., 2002, pp 998-1008, Vol., 19(7)	
	43	FERNANDEZ-URRUSUNO, R., et al, "Enhancement of Nasal Absorption of Insulin Using Chitosan Nanoparticles", Pharm Res., 1999 Oct., pp1576-1581, Vol. 16(10)	
	44	ILLUM, L., et al, "Chitosan as a Novel Nasal Delivery System for Peptide Drugs", Pharm Res., 1994 Aug, pp 1186-1189, Vol. 11(8)	
	45	KYTE, J., et al, "A Simple Method for Displaying the Hydrophobic Character of a Protein", J Mol Biol., 1982 May, pp 105-132, Vol. 157(1)	
	46	McEWAN, G.T., et al, "Polycation-Induced Enhancement of Epithelial Paracellular Permeability...", Biochem Biophys Acta., 1993 May 14, pp 51-60, Vol. 1148(1)	
	47	MIYAMOTO, M., et al, "Improved Nasal Absorption of Drugs Using Poly-L-Arginine: Effects of Concentration...", Eur J Pharm Biopharm, 2001 July, pp 21-30, Vol. 52(1)	
	48	MIYAMOTO, M., et al, "Effect of Poly-L-Arginine on the Nasal Absorption...", Int J Pharm., 2001 Sep 11, pp 127-138, Vol. 226(1-2)	
/J.H./	49	NATSUME, H., et al, "Screening of Cationic Compound as an Absorption Enhancer...", Int J Pharm., 1999 Aug 5, pp 1-12, Vol. 185(1)	

Examiner Signature	/Julie Ha/	Date Considered	07/17/2008
--------------------	------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/559,595
Filing Date	November 30, 2005
First Named Inventor	ONG, John, et al
Art Unit	1654
Examiner Name	Not Yet Assigned Julie Ha
Attorney Docket Number	0501-UTL-0

Sheet

4

of

4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/J.H./	50	OHTAKE, K., et al, "Analysis of Transient and Reversible Effects of Poly-L-Arginine on the In Vivo Nasal...", J Control Release, 2002 Aug 21, pp 263-275, Vol. 82(2-3)	
/J.H./	51	OHTAKE, K., et al, "Poly-L-Arginine Enhances Paracellular Permeability Via Serine/Threonine Phosphorylation..." Pharm Res., 2003 Nov., pp1838-1845, Vol. 20(11)	
/J.H./	52	UCHIDA, D.A., et al, "Cationic Proteins Increase the Permeability of Cultured Rabbit Tracheal Epithelial..." Exp Lung Res., 1996 Jan - 1996 Feb, pp 85-99, Vol. 22(1)	

Examiner
Signature

/Julie Ha/

Date
Considered

07/17/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.